

510(k) Summary

K132030

Date Prepared: June 27th, 2013

Applicant: Medtronic Ireland
Parkmore Business Park West
Galway
Ireland

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SEP 27 2013

Proprietary Name: MicraTM Introducer

Model: MI2355A

Device Classification: Class II

Regulation Number: 21 CFR 870.1340

Classification Name: Catheter Introducer

Product Code: DYB

Summary of
Technological
Differences
between the
Micra™
Introducer and
the Predicate
Device:

Characteristics	Medtronic Micra™ Introducer	Medtronic Sentrant Introducer Sheath
Intended Use	Intended to provide a conduit for the insertion of devices into the venous system and to minimize blood loss associated with such insertions.	Intended to provide a conduit for the insertion of diagnostic or endovascular devices into the vasculature and to minimize blood loss associated with such insertions.
Sheath Diameters (size of device that fits into sheath)	23F	12F-26F (2F increments)
Sheath Working Length	55.7 cm	28cm and 64cm

Summary of
Studies:

The following in-vitro bench tests were completed on the Micra™ Introducer and verify that it meets the required performance specifications:

- Dimensional measurement
- Tensile testing
- Hemostatic Leak Test
- Kink Test
- Liquid leakage under pressure
- Coating Presence and Coating Integrity
- Side Port Torque

The Micra™ Introducer met all specified design and performance requirements.

Summary of
Clinical Data:

No clinical investigation has been performed for this device.

Biocompatibility
Information:

Biocompatibility testing for the Micra™ Introducer has been completed in accordance with the International Standard ISO10993-1:2009 "Biological Evaluation of Medical devices-Part 1: Evaluation and Testing" for an external communicating device with limited exposure i.e. whose contact with circulating blood is ≤ 24 hours.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 27, 2013

Medtronic Inc.
Ms. Chechamma Varughese
Principal Regulatory Affairs Specialist
Cardiac Rhythm Disease Management (CRDM)
8200 Coral Sea Street, MVS11
Mounds View, MN 55112

Re: K132030
Trade/Device Name: Micra introducer sheath with hydrophilic coating
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II
Product Code: DYB
Dated: July 3, 2013
Received: July 8, 2013

Dear Ms. Varughese:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K132030

Device Name: Micra™ Introducer


Indications for Use: The Micra introducer is intended to provide a conduit for the insertion of devices into the venous system and to minimize blood loss associated with such insertions.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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